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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,535	08/15/2001	Raymond F. Cracauer	FORS-06449	2205
23535	7590	02/15/2005	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			NAGPAUL JYOTI	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,535

Applicant(s)

CRACAUER ET AL.

Examiner

Jyoti Nagpaul

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-96 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 85-95 have been renumbered to 86-96.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 35-42, 51, 61, 66, 71, and 86-88** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: it is unclear and indefinite as to how the synthesizer is configured to produce the number of claimed compounds.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

5. **Claims 1-34,43-45,48-50,52-60,62,68-70,72-74,75-85,and 89-96** are rejected under 35 U.S.C. 102 as being anticipated by Zelinka (US 4598049).

Zelinka teaches an automated system comprising a closed system nucleic synthesizer configured for parallel synthesis of three or more polymers. (Col. 7, Lines 14-16). Zelinka further teaches a controlled gene synthesizer for programmably synthesizing selected nucleotide sequences. The apparatus operates to sequentially wash and dry the contents of the cell, expose nucleotide reaction sites, add and couple bases at the reaction sites and cap or protect the reaction sites by a robotic component. Some of the functions related to operator programming of a desired DNA coupling sequence include selecting various ones or combinations of the individuals basses; adding the selected bases or combinations to the reaction cell with appropriate preparation and washout step; performing the washing of the reaction cell for the next base addition. (Lines 61-3, Col. 17-18) Zelinka describes base addition includes refilling of syringes, performing a pyrindine wash and nitrogen blow down of the reaction cell, capping the ends of the nucleotide sequences, cell temperature control and resetting the elapsed time counter. Zelinka also discusses means for heating the reaction cell to promote the growth process. (Lines 56-57, Col. 2) The temperature controller provides the operator with pertinent temperature information as it relates to the reaction cell. The temperature controller generally monitors the temperature of the reaction cell and which is heated by an epoxy encapsulated thin film heater element that is wrapped around the reaction cell. With respect to Claims 63-69,70,72, and 78, Zelinka teaches temperature control and is clearly capable of operating with in the

recited temperature range. "Providing an optimized reaction temperature" is considered an intended use of the apparatus and is not accorded patentable weight in claims to that apparatus. The temperature is set and read via a set/read switch. (Lines 55-68, Col. 5) Zelinka describes this process continues until desired growth oligonucleotide is chemically separated from the solid support material. (Lines 22-20, Col. 2) Zelinka describes a fluid circuit exists from source to waste at any time reagents are being transferred. Zelinka discloses a plurality of syringe bodies/ reagent dispensers or pressurized containers for delivery of reagents. (Col. 6, Lines 12-16) (Col. 5, Lines 8-10) Zelinka further discloses agitating/mixing means. (Col. 4, Lines 38-39)(Col. 6, Lines 27-30) Zelinka teaches isolation is achieved via a valve body V17 that acts as a selector valve for the solvent bottles. (Lines 52-55, Col. 11) The enablement of the valve body V17, only one or desired simultaneous combination of the solvent/reagents is selected and directed to valve body V26. Depending on the position of valve body V26 the liquid is again selectively directed either through reaction cell 14 to valve body V27 and then to collection or waste; or is blocked from flowing through cell 14 and in which case a nitrogen or argon gas purge is directed from the top of the cell 14. (Lines 57-65, Col. 11, Refer to Fig. 6) Therefore, comprising of a closed system. Zelinka further discloses a detrtylation step and fro which the chemicals are delivered to an external collector and tested via known techniques and spectrophotometric test and recording apparatus. (Col. 5, Lines 22-26) With respect to Claim 34, Zelinka discloses a plurality of injectors that are simultaneously actuable. (Claim 1, Lines 30-32) Thus, it reasonably

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appears that Zelinka describes or discloses every element of the claim and therefore anticipates the claims subject to this rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 46 and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelinka.

Zelinka fails to teach the computer memory further comprises of allele frequency information and disease association information. However, Zelinka teaches an automated gene synthesizer. Thus, a gene comprises different types of genetic information, such as allele frequency and disease association. The synthesizer is controlled by a microprocessor that contains memory and can be programmed to include all types of different genetic information. It would also have been obvious to one of ordinary skill in this art at the time of the invention by applicant to modify the system of Zelinka such that the computer memory further comprises of allele frequency and disease association information in order to provide insight into the causes and mechanisms of a large variety of disease and conditions.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN


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